

SIU 7396

PATENT

**BEST AVAILABLE COPY**

In order to establish a *prima facie* case of obviousness, the Patent Office must demonstrate that the prior art references provide the necessary teaching, suggestion or motivation for one of ordinary skill in the art to make the claimed invention. See MPEP 2143.01; In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992). The cited reference, Campbell et al., describes the administration of D-methionine to male rats for the prevention of ototoxicity caused by cisplatin, a chemotherapeutic agent having known ototoxic effects. In making the rejection final, the Examiner relies on his rejection in Paper No. 7 wherein it was stated that the reference's teaching provides sufficient motivation for one skilled in the art to use the claimed compounds for treating ototoxicity caused by any means including noise. However, Applicant respectfully submits that any such inference is based entirely on an impermissible hindsight analysis. The cited reference is entirely devoid of any teaching or suggestion of ototoxicity caused by exposure to noise. Thus, it is respectfully submitted that one skilled in the art reading the cited reference at the time of the invention would not be led to select the claimed compounds for the treatment of ototoxicity caused by noise without reference to Applicant's own discovery and disclosure. Accordingly, it is respectfully submitted that Campbell et al. do not provide the necessary teaching, suggestion or motivation to lead one skilled in the art to practice the invention of instant claim 1. Withdrawal of the rejection is respectfully requested.

Further, the Examiner appears to offer an alternative basis for rejecting the claims under 35 U.S.C. §103(a) in the final Office action. In rebutting Applicant's comments dated 17 April 2003, the Examiner appears to articulate that the cited reference does teach ototoxicity caused by exposure to noise by stating that "Applicant states that the Campbell et al. reference does not contain ototoxicity caused by exposure to noise. This is not correct since the reference contains 'toneburst stimuli' and the instant claims are directed to 'preventing' the condition."

SIU 7396  
PATENT

Although this position appears to be contrary to that taken in Paper No. 7 wherein the Examiner conceded that "the only difference [between the cited reference and the instant claims] is that the ototoxicity is caused by other than noise" (See page 3, line 1 of Paper No. 7), Applicant has chosen to address the cited passage so as to be fully responsive to the Office action.

As stated above, the cited reference describes the administration of D-methionine for the treatment or prevention of ototoxicity in male rats receiving chemotherapeutic doses of cisplatin. To evaluate the results of the testing, Campbell et al. administered hearing tests to the male rats being studied. The hearing tests involved the use of "toneburst stimuli" and ABR threshold shift analysis, which are standard, diagnostic hearing tests known to those skilled in the art. While such diagnostic testing is admittedly an exposure to noise, such hearing tests are conducted at an intensity and for a duration that falls well short of the claimed limitation requiring "exposure to noise for a time and at an intensity sufficient to result in ototoxicity." Thus, it is respectfully submitted that one skilled in the art would not interpret the diagnostic hearing tests employed by Campbell et al. as sufficient teaching or motivation of ototoxicity caused by exposure to noise.

Because the reference is entirely devoid of any mention of ototoxicity caused by exposure to noise as required by the instant claims and nothing in the reference remotely teaches or suggests what effect, if any, D-methionine would have with respect to ototoxicity caused by exposure to noise, it is respectfully submitted that the cited reference, Campbell et al., does not provide any teaching, suggestion or motivation for practicing the claimed invention. Accordingly, Applicant respectfully submits that the reference relied on by the Examiner fails to establish a *prima facie* case of obviousness with respect to claim 1. Withdrawal of the rejection and early allowance is respectfully requested.

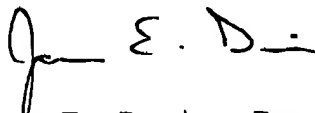
SIU 7396  
PATENT

Claims 3-41, which are further directed to treating or preventing ototoxicity resulting from exposure to noise, are likewise submitted as patentable for the reasons set forth above.

Conclusion

It is not believed that any fee is required by the timely submission of this response. However, the Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment of fees to Deposit Account No. 19-1345 in the name of Senniger, Powers, Leavitt & Roedel.

Respectfully submitted,



James E. Davis, Reg. No. 47,516  
SENNIGER, POWERS, LEAVITT & ROEDEL  
One Metropolitan Square, 16th Floor  
St. Louis, Missouri 63102  
(314) 231-5400

JED/clh

VIA FACSIMILE - 703-305-3592

**OFFICIAL****RECEIVED  
CENTRAL FAX CENTER**

SEP 16 2003